



PTO/SB/08a/b (08-03)  
Approved for use through 07/31/2008. OMB 0651-0031  
U.S. Patent and Trademark Office; U.S. DEPARTMENT OF COMMERCE  
Under the Paperwork Reduction Act of 1995, no persons are required to respond to a collection of information unless it contains a valid OMB control number.

|   |   |    |                          |                        |              |
|---|---|----|--------------------------|------------------------|--------------|
| <b>INFORMATION DISCLOSURE<br/>STATEMENT BY APPLICANT</b><br><br>(Use as many sheets as necessary) |   |    | <b>Complete if Known</b> |                        |              |
|   |   |    | Application Number       | 10/686,517             |              |
|   |   |    | Filing Date              | October 16, 2003       |              |
|   |   |    | First Named Inventor     | Amar LULLA et al.      |              |
|   |   |    | Art Unit                 | 1619                   |              |
|   |   |    | Examiner Name            | C. OSTRUP              |              |
| Sheet   | 1 | of | 1                        | Attorney Docket Number | 33396-198024 |

| U.S. PATENT DOCUMENTS |                          |  |                                |  |   |
|-----------------------|--------------------------|--|--------------------------------|--|---|
| Examiner<br>Initials* | Cite<br>No. <sup>1</sup> | Document Number                          | Publication Date<br>MM-DD-YYYY | Name of Patentee or<br>Applicant of Cited Document | Pages, Columns, Lines, Where<br>Relevant Passages or Relevant<br>Figures Appear |
|                       |                          | Number-Kind Code <sup>2</sup> (if known) |                                |  |   |
|                       | A1                       | 5,725,491                                | 03-10-1998                     | Tipton et al.                                      |   |
|                       | A2                       | 5,980,921                                | 11-09-1999                     | Biedermann et al.                                  |   |
|                       | A3                       |  |                                |  |   |
|                       | A4                       |  |                                |  |   |
|                       | A5                       |  |                                |  |   |
|                       | A6                       |  |                                |  |   |
|                       | A7                       |  |                                |  |   |
|                       | A8                       |  |                                |  |   |

| FOREIGN PATENT DOCUMENTS |                          |   |                                   |  |   |                |
|--------------------------|--------------------------|---|-----------------------------------|--|---|----------------|
| Examiner<br>Initials*    | Cite<br>No. <sup>1</sup> | Foreign Patent Document   | Publication<br>Date<br>MM-DD-YYYY | Name of Patentee or<br>Applicant of Cited Document | Pages, Columns, Lines,<br>Where Relevant Passages<br>or Relevant Figures Appear | T <sup>6</sup> |
|                          |                          | Country Code <sup>3</sup> -Number <sup>4</sup> -Kind Code <sup>5</sup> (if known) |                                   |  |   |                |
|                          | B1                       |   |                                   |  |   |                |
|                          | B2                       |   |                                   |  |   |                |
|                          | B3                       |   |                                   |  |   |                |
|                          | B4                       |   |                                   |  |   |                |
|                          | B5                       |   |                                   |  |   |                |

\*EXAMINER: Initial if reference considered, whether or not citation is in conformance with MPEP 609. Draw line through citation if not in conformance and not considered. Include copy of this form with next communication to applicant. <sup>1</sup> Applicant's unique citation designation number (optional). <sup>2</sup> See Kinds Codes of USPTO Patent Documents at [www.uspto.gov](http://www.uspto.gov) or MPEP 901.04. <sup>3</sup> Enter Office that issued the document, by the two-letter code (WIPO Standard ST.3). <sup>4</sup> For Japanese patent documents, the indication of the year of the reign of the Emperor must precede the serial number of the patent document. <sup>5</sup> Kind of document by the appropriate symbols as indicated on the document under WIPO Standard ST.16 if possible. <sup>6</sup> Applicant is to place a check mark here if English language Translation is attached.

| NON PATENT LITERATURE DOCUMENTS |                          |   |                |
|---------------------------------|--------------------------|---|----------------|
| Examiner<br>Initials            | Cite<br>No. <sup>1</sup> | Include name of the author (in CAPITAL LETTERS), title of the article (when appropriate), title of the item (book, magazine, journal, serial, symposium, catalog, etc.), date, page(s), volume-issue number(s), publisher, city and/or country where published. | T <sup>2</sup> |
|                                 | C1                       |   |                |
|                                 | C2                       |   |                |
|                                 | C3                       |   |                |
|                                 | C4                       |   |                |
|                                 | C5                       |   |                |

\*EXAMINER: Initial if reference considered, whether or not citation is in conformance with MPEP 609. Draw line through citation if not in conformance and not considered. Include copy of this form with next communication to applicant.

<sup>1</sup> Applicant's unique citation designation number (optional). <sup>2</sup> Applicant is to place a check mark here if English language Translation is attached.

|                       |  |                    |         |
|-----------------------|--|--------------------|---------|
| Examiner<br>Signature |  | Date<br>Considered | 1/30/07 |
|-----------------------|--|--------------------|---------|

::ODMA\PCDOCS\DC2DOCS\1578623\1

10/16/03

|   |   |  |
|---|---|--|
| <b>FORM PTO-1449</b><br><b>INFORMATION DISCLOSURE STATEMENT</b> | <b>Atty Docket:</b><br>33396-198024     | <b>Application No.</b><br>To be Assigned<br><br><b>Continuation of</b><br>Application No. 09/503,843 |
|   | <b>Applicants:</b> LULLA et al          |  |
|   | <b>Filing Date:</b><br>October 16, 2003 | <b>Art Unit:</b> 1614  |

**U.S. PATENT DOCUMENTS**

| Examiner Initial |    | Document Number | Date       | Name              | Class | Sub-Class | Filing Date |
|------------------|----|-----------------|------------|-------------------|-------|-----------|-------------|
| WZ               | AA | 3,476,853       | 11/04/1969 | Jatul et al.      |       |           |             |
|                  | AB | 4,534,958       | 08/13/1985 | Adams et al.      |       |           |             |
|                  | AC | 4,293,542       | 10/06/1981 | Lang et al.       |       |           |             |
|                  | AD | 4,704,406       | 11/03/1987 | Stanislaus et al. |       |           |             |
|                  | AE | 5,413,792       | 5/9/1995   | Ninomiya et al    |       |           |             |
|                  | AF | 5,474,783       | 12/12/1995 | Miranda et al     |       |           |             |
|                  | AG | 3,932,602       | 1/13/1976  | Sweger            |       |           |             |
|                  | AH | 4,316,887       | 2/23/1982  | Kamishita         |       |           |             |
|                  | AI |                 |            |                   |       |           |             |

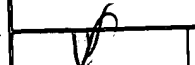

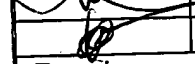
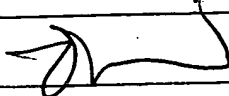
**FOREIGN PATENT DOCUMENTS**

|    |    | Document Number | Publication Date | Country       | Class | Sub-Class | Translation |
|----|----|-----------------|------------------|---------------|-------|-----------|-------------|
| WZ | AJ | 0761095         | 03/12/97         | EUROPE        |       |           | No          |
|    | AK | 0679390         | 11/02/95         | EUROPE        |       |           |             |
|    | AL | 0619115         | 10/12/94         | EUROPE        |       |           |             |
|    | AM | 0055397         | 07/07/82         | EUROPE        |       |           |             |
|    | AN | 0356196         | 28/02/90         | EUROPE        |       |           |             |
|    | AO | 1372721         | 6/11/74          | GREAT BRITAIN |       |           |             |
|    | AP | 1175355         | 12/4/81          | CANADA        |       |           |             |
|    | AQ | WO00/10540      | 3/2/2000         | WIPO          |       |           |             |
|    | AR | WO97/01327      | 1/16/97          | WIPO          |       |           |             |
|    | AS | WO98/23291      | 6/4/98           | WIPO          |       |           |             |
|    | AT | 0 713 708       | 5/29/96          | Europe        |       |           |             |
|    | AU | 0 390 541       | 10/3/90          | Europe        |       |           |             |
|    | AV | WO96/33689      | 10/96            | WIPO          |       |           |             |
|    |    |                 |                  |               |       |           |             |

Examiner

Date Considered

EXAMINER: Initial if reference considered, whether or not citation is in conformance with MPEP 609; draw line through citation if not in conformance and not considered. Include copy of this form with next communication to Applicant.

|   |           |   |  |
|---|-----------|---|--|
| <b>FORM PTO-1449</b><br><b>INFORMATION DISCLOSURE</b><br><b>STATEMENT</b>   |           | <b>Atty Docket:</b><br>33396-198024   | <b>Application No.</b><br><b>To be Assigned</b><br><br><b>Continuation of</b><br><b>Application No: 09/503,843</b> |
|   |           | <b>Applicants:</b> LULLA et al  |  |
|   |           | <b>Filing Date:</b><br>October 16, 2003   | <b>Art Unit:</b> 1614  |
| <b>OTHER (Including Author, Title, Date, Pertinent Pages, etc.)</b>   |           |   |  |
|    | <b>AW</b> | Jenny McElroy, "Victorian School of Pharmacy develops spray-on drugs," New Zealand Pharmacy, p.3, November 1999.              |  |
|    | <b>AX</b> | "Isocard Transdermal Spray", ABPI Compendium of Data Sheets and Summaries of Product Characteristics p. 306. <i>pub. date</i> |  |
|    | <b>AY</b> |   |  |
| <b>Examiner</b>    |           |   | <b>Date Considered</b><br>6/3/07   |
| <b>EXAMINER:</b> Initial if reference considered, whether or not citation is in conformance with MPEP 609, draw line through citation if not in conformance and not considered. Include copy of this form with next communication to Applicant. |           |   |  |

| <b>FORM PTO-1449</b><br><br><b>INFORMATION DISCLOSURE</b><br><b>STATEMENT</b>   |                 | <b>Atty Docket:</b><br><br>33396-198024 |           | <b>Application No.</b><br>To be Assigned<br><br><b>Continuation of</b><br>Application No. 09/503,843 |                                   |             |
|---|-----------------|---|-----------|--|-----------------------------------|-------------|
|   |                 | <b>Applicants:</b> LULLA et al          |           |  |                                   |             |
|   |                 | <b>Filing Date:</b><br>October 16, 2003 |           | <b>Art Unit:</b> 1614  |                                   |             |
| <b>U.S. PATENT DOCUMENTS</b>  |                 |   |           |  |                                   |             |
| Examiner Initial  | Document Number | Date                                    | Name      | Class  | Sub-Class                         | Filing Date |
| ✓   | BA              | 4,826,677                               | 5/2/1989  | Mueller et al.   |                                   |             |
|   | BB              |   |           |  |                                   |             |
|   | BC              |   |           |  |                                   |             |
|   | BD              |   |           |  |                                   |             |
|   | BE              |   |           |  |                                   |             |
|   | BF              |   |           |  |                                   |             |
|   | BG              |   |           |  |                                   |             |
|   | BH              |   |           |  |                                   |             |
|   | BI              |   |           |  |                                   |             |
| <b>FOREIGN PATENT DOCUMENTS</b>   |                 |   |           |  |                                   |             |
|   | Document Number | Publication Date                        | Country   | Class  | Sub-Class                         | Translation |
| ✓   | BJ              | WO88/09185                              | 12/1/1988 | WIPO   |                                   |             |
|   | BK              | EP 0 756 870                            | 5/2/1997  | Europe   |                                   |             |
|   | BL              | WO96/30000                              | 10/3/1996 | WIPO   |                                   |             |
|   | BM              | EP 0 617 972                            | 10/5/1994 | Europe   |                                   |             |
| ✓   | BN              | EP 0 055 396                            | 7/7/1982  | Europe   |                                   |             |
|   | BN              | EP 0 521 455                            | 1/7/1993  | Europe   |                                   |             |
|   | BO              |   |           |  |                                   |             |
|   | BP              |   |           |  |                                   |             |
|   | BQ              |   |           |  |                                   |             |
|   | BR              |   |           |  |                                   |             |
|   | BS              |   |           |  |                                   |             |
|   | BT              |   |           |  |                                   |             |
|   | BU              |   |           |  |                                   |             |
| <b>Examiner</b>   |                 |   |           |  | <b>Date Considered</b><br>1/31/07 |             |
| <b>EXAMINER:</b> Initial if reference considered, whether or not citation is in conformance with MPEP 609; draw line through citation if not in conformance and not considered. Include copy of this form with next communication to Applicant. |                 |   |           |  |                                   |             |